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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,891

06/22/2006

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EXAMINER

HORNING, MICHELLE S

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,891	<b>Applicant(s)</b> BENSIK-REYNIER ET AL.	
	<b>Examiner</b> MICHELLE HORNING	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Double Patenting-NECESSITATED BY AMENDMENTS***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 18-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of U.S. Patent No. 7217530 in view of Koga et al (2003) and Kiesewetter (WO 02/065133, US 2004/0096902 relied on as a US equivalent).** Although the conflicting claims are not identical, they are not they are patentably distinct from each other because the macrocyclic chelating agent used for PrP detection in the method of the instant claims 18-24 are also claimed in the ‘530 patent for PrP detection. The claims of the ‘530 patent are drawn to an anti-PrPsc antibody for PrPsc detection. The claims of the ‘530

Art Unit: 1648

patent do not include adding or using polyallylamine, proteinase K, separating and denaturing PrP aggregates and a solid support.

Koga et al provides a method for amyloid fibril formation using a poly (gamma-methyl-L-glutamate)-conjugated polyallylamine (see Introduction, page 6). The authors provide that using the described method leads to peptide self-assembles into nonbranching fibrils under certain conditions (see Abstract). The fibrils are rich in beta-sheets (Abstract). Lastly, Koga et al teach that the method allows for the control of the assemble structure of peptides (Abstract).

The '902 patent discloses a method of detecting PrP in biological samples which comprises the use of a detection compound that binds PrP, which are similar to the methods in the '530 patent. The '902 patent teaches a method wherein the PrP is first treated with proteinase K, as a denaturant, that the ligand is bound to a solid support and separating the denaturing PrP aggregates and detecting them in the sample, which provides the advantage of an effective reaction assay; see page 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in the '530 patent to further include the conjugated polyallylamine as described by Koga et al as well as the steps taught in '902. One would have been motivated to do so in order to increase fibril formation of the PrP protein. Further, the '902 patent teaches that the described steps allow for a simple, rapid and effective assay for detecting PrP. Note that the instant claims do not require the PrP protein to be in any specific conformation (e.g. alpha or beta-formation). Note that it would have been obvious to the ordinary artisan to alter the

sequence of steps (e.g. adding an ingredient first or second with respect to a different ingredient) in order to optimize results; see MPEP 2144.04. There would have been a reasonable expectation of success given the described methods have shown to be successful.

**Claims 18-24 and 28-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of U.S. Patent No. 7217530 in view of US Application 11/151, 066 (2006/0014215, Moussa et al) and Kieseewetter (WO 02/065133, US 2004/0096902 relied on as a US equivalent).** Although the conflicting claims are not identical, they are not patentably distinct from each other because the macrocyclic chelating agent used for PrP detection in the method of the instant claims 18-24 are also claimed in the '530 patent for PrP detection. The claims of the '530 patent are drawn to an anti-PrPsc antibody for PrPsc detection. The claims of the '530 patent do not include adding or using streptomycin, proteinase K, separating and denaturing PrP aggregates and a solid support.

US Application '066 by common inventors discloses a process for detecting PrPsc by adding streptomycin (see claims 1 and 9). Claim 1 is drawn to the aminoglycoside (streptomycin) complexing with PrPsc, leading to its detection.

The '902 patent discloses a method of detecting PrP in biological samples which comprises the use of a detection compound that binds PrP, which are similar to the methods in the '530 patent. The '902 patent teaches a method wherein the PrP is first treated with proteinase K, as a denaturant, that the ligand is bound to a solid support

Art Unit: 1648

and separating the denaturing PrP aggregates and detecting them in the sample, which provides the advantage of an effective reaction assay; see page 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in the '530 patent to further include streptomycin as described by the inventors of the '066. One would have been motivated to do so given it is known to complex to PrP protein which would lead to a greater signal of detection. Further, the '902 patent teaches that the described steps allow for a simple, rapid and effective assay for detecting PrP. Note that the instant claims do not require the PrP protein to be in any specific conformation (e.g. alpha or beta-formation). Also, it would have been obvious to the ordinary artisan to alter the sequence of the steps (e.g. adding an ingredient first or second with respect to a different ingredient) in order to optimize results; see MPEP 2144.04. There would have been a reasonable expectation of success given the described methods have shown to be successful.

**Claims 18 and 25-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-14 of copending Application No. 11/701, 334 in view of US Application 11/151, 066 (2006/0014215, Moussa et al).**

**Note that the claims of the '334 application are inadvertently dependent upon a cancelled method claim 9, while claims 10-14 are drawn to the same macrocyclic ligand without any active steps. This macrocyclic ligand is described by the specification to be used in a process for the detection of prion pathogens.**

Art Unit: 1648

**Further, claims of the '334 application including claims 17 and 18 are drawn to a diagnostic kit for PrPsc comprising this ligand, providing support that this ligand is used for PrPsc detection.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of the claims are drawn to the same general formula of macrocyclic ligand used in a method for PrP detection. Also note that the instant claim 18 is broad which encompasses the specific ligand of instant claim 25. This application does not disclose adding streptomycin.

US Application '066 by common inventors discloses a process for detecting PrPsc by adding streptomycin (see claims 1 and 9). Claim 1 is drawn to the aminoglycoside (streptomycin) complexing with PrPsc, leading to its detection.

It would have been obvious to one of ordinary skill in the art to contact a biological sample with this macrocyclic ligand in combination with streptomycin, given both lead to PrP detection and a combination would further amplify the detection signal. Note that the instant claims are not drawn to any specific conformation of PrP and the protein may be in its infectious or native state. There would have been a reasonable expectation of success given both the ligand and streptomycin successfully lead to PrP detection.

This is a provisional obviousness-type double patenting rejection.

***Conclusion***

No claims are allowed. No Terminal Disclaimers were filed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHELLE HORNING** whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/  
Examiner, Art Unit 1648  
/Bruce Campell/  
Supervisory Patent Examiner, Art Unit 1648